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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,398	08/28/2001	Constance Mary John	3157.00006	6148

7590 06/29/2005

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,398	JOHN, CONSTANCE MARY	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 3/30/05.

Claims 2-6, 9, and 11-24 have been canceled.

Claims 1, 7, 8, and 10 remain pending.

This Action is NON-FINAL due to new grounds of rejection not necessitated by Applicant's amendments.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It was not executed in accordance with either 37 CFR 1.66 or 1.68. The oath is unsigned.

At page 15 of the response received 8/13/04, Applicant indicated that a signed oath was enclosed with the response. The PTO failed to find this document and scan it into the electronic file. The Examiner appreciates Applicant's efforts in faxing a copy of the signed Declaration directly to the Examiner, however all faxed correspondence for entry into the application must be directed to the central office fax at 703-872-9306. Applicant is invited to submit the signed oath to the central fax, or to include it with the next Response. Because an Action in this Application is due immediately, any submitted oath will be considered in the next Action.

Specification

The specification stands objected to because it is 128 pages in length but lacks pages numbered 94-99, while containing pages numbered 1-93 and 100-134. Applicant should file an amendment to the specification correcting the page numbering. At page 15 of the response filed 8/13/04, Applicant indicates that "the missing pages" were enclosed. This attachment was not found by the PTO. Applicant is advised that such a submission would be carefully considered for the presence of new matter and objected to if necessary.

Claim Objections

The objection to claim 12 is overcome by Applicant's amendment.

Rejections Withdrawn

The rejection of claims 1, 7, 8, and 10 for lack of enablement is withdrawn in view of Applicant's amendment limiting the scope of the Sertoli cells to those that express neurotrophins.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gage et al (US Patent 5,082,670, issued 1/21/92) in view of Sanberg et al (US Patent 5,702,700, issued 3/13/95).

Gage taught a method of treating defective, diseased or damaged cells in the mammalian central nervous system comprising grafting donor cells from the same mammalian species into the central nervous system, said donor cells genetically modified to produce nerve growth factor (NGF) in a sufficient amount to ameliorate said defective, diseased or damaged cells in the central nervous system. See claim 18 and paragraph bridging columns 12 and 13. Gage taught a variety of methods of nucleic acid delivery to donor cells including retroviral (claims 8-10) adenoviral (column 11, line 59), microinjection (claim 12), electroporation (claim 13), calcium phosphate precipitation (claim 15), and liposomal transfection (column 12, lines 3-12).

Gage did not teach the use of Sertoli cells.

Sanberg suggested the use of Sertoli cells as an in situ factory for producing neurotrophic factors.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use Sertoli cells as donor cells in the invention of Gage. One would have been motivated to do so because Sanberg taught that one significant benefit of utilizing Sertoli cells as an in situ factory for producing neurotrophic factors is that Sertoli cells have been shown to have an effective immunosuppressant effect. Accordingly, concomitant adjunctive therapy to produce immunosuppression is not required. In other words, the Sertoli cells can be used as a trophic factor source while also providing a

self-induced local immunosuppressive effect. See column 2, lines 37-45. One would have been further motivated to use Sertoli cells because, as taught by Sanberg, they naturally secrete neurotrophic factors other than NGF, such as insulin like growth factors, and would therefore provide additional beneficial effects. See Table 1 at column 5, line 22.

Thus the invention as a whole was prima facie obvious.

Claims 1, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gage et al (US Patent 5,082,670, issued 1/21/92) in view of Sanberg et al (US Patent 5,702,700, issued 3/13/95) and March et al (US Patent 5,840,059, issued 11/24/98).

The teachings of Gage and Sanberg are discussed above. Gage taught a method of treating defective, diseased or damaged cells in the mammalian central nervous system comprising grafting donor cells from the same mammalian species into the central nervous system, said donor cells genetically modified by viral or non-viral means to produce nerve growth factor (NGF) in a sufficient amount to ameliorate said defective, diseased or damaged cells in the central nervous system. Sanberg suggested the use of Sertoli cells as an in situ factory for producing neurotrophic factors. These references render obvious methods of using genetically modifying Sertoli cells to secrete NGF, and surgically implanting the Sertoli cells in the CNS of a patient.

These references do not teach delivery of nucleic acids to Sertoli cells by adeno-associated virus (AAV).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use an adeno-associated virus vector to deliver the NGF gene of Gage to the Sertoli cells of Sanberg. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. See also Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). In this case, March taught that microinjection, electroporation, calcium phosphate precipitation, lipofection, retroviral transduction, adenoviral transduction, and AAV transduction were all interchangeable means of delivering gene therapy agents. As such it was recognized in the art that AAV was an equivalent means of gene delivery to the other methods disclosed in Gage.

As discussed above, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the Sertoli cells of Sanberg as donor cells in the invention of Gage. One would have been motivated to do so because Sanberg taught that one significant benefit of utilizing Sertoli cells as an in situ factory for producing neurotrophic factors is that Sertoli cells have been shown to have an effective

immunosuppressant effect. Accordingly, concomitant adjunctive therapy to produce immunosuppression is not required. In other words, the Sertoli cells can be used as a trophic factor source while also providing a self-induced local immunosuppressive effect. See column 2, lines 37-45. One would have been further motivated to use Sertoli cells because, as taught by Sanberg, they naturally secrete neurotrophic factors other than NGF, such as insulin like growth factors, and would therefore provide additional beneficial effects. See Table 1 at column 5, line 22.

Thus the invention as a whole was prima facie obvious.

Conclusion

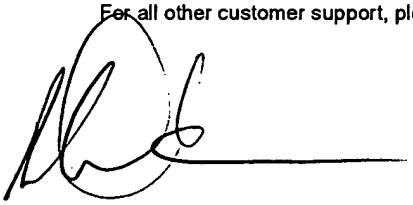
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.